

II. Remarks

A. Finality of Office Action

In Applicant's response to the July 7, 2010 Office Action, claims 1, 7, 8, 11-13, 16, 24-27, 30, 34, 38, 41-43, 46, 51 (incorrectly numbered), and 52 (incorrectly numbered) were amended, and new claims 52-54 were added. Such amendments and new claims were for purposes of providing clarity to the nature of the invention being claimed and did not expand claim scope or involve switching from one subject matter to another. Moreover, Applicant responded to every rejection, including a rejection under 35 USC §102(b). In some cases, a detailed response was not required because the aforementioned claim amendments rendered the rejection moot.

In the present Office action, the Examiner has made a new rejection under 35 USC §102(b) with art (Rajan) that was not the subject matter of the previous Office Action. In fact, in July 7, 2010 Office action, the Examiner lists Rajan as "prior art made of record and not relied upon" *See*, page 6.

Despite the aforementioned, the Examiner has made the present Office Action final, stating "Applicant's amendment necessitated the new ground(s) of rejection present in this Office Action." *See*, page 6. However, Applicants assert that the Examiner has improperly made the present Office Action final. As directed by MPEP §706.07(a), "[b]efore final rejection is in order a clear issue should be developed between the examiner and applicant. . . . [Switching] from one set of references to another by the examiner in rejecting in successive actions claims of substantially the same subject matter, will alike tend to defeat attaining the goal of reaching a clearly defined issue for an early termination, i.e., either an allowance of the application or a final rejection."

In response to the July 7, 2010 Office action, Applicants made amendments that were intended to clarify the nature of the claimed invention, and did not switch from one subject matter to another. Thus, a final Office action based upon said amendments is improper, especially when Applicants responded to each rejection and/or objection in the previous Office

action. Moreover, a final Office action is improper when Applicants have not yet had a chance to make arguments about Rajan and develop a “clear issue” between the Examiner and Applicants. As directed by MPEP §706.07(a), “present practice does not sanction hasty and ill-considered final rejections. The applicant who is seeking to define his or her invention in claims that will give him or her the patent protection to which he or she is justly entitled should receive the cooperation of the examiner to that end, and not be prematurely cut off in the prosecution of his or her application.”

In light of the aforementioned, Applicants respectfully request that the Examiner remove the finality of the present Office action and enter the current amendments to the claims which are believed to address all grounds of rejection/objection, including the new grounds, and which are believed to place the application in condition for allowance.

Because Applicants assert that the finality of the present Office action is improper, Applicants do not believe that entry of the Information Disclosure Statement (IDS) submitted herewith requires that a RCE be filed. Thus, Applicants have submitted said IDS with the fee set forth in 37 CFR §1.17(p).

B. Claims

Claims 1, 7, 8, 11-13, 16, 24-27, 30, 34, 38, 40-43, 46, and 50-54 are pending in the application.

Applicants have cancelled claims 11-13, 16, 30, and 52 without prejudice or disclaimer.

Applicants have amended claim 1 for purposes of clarity, and not for purposes of patentability. Notably, Applicants have amended the claim to clarify (i) that the method is directed at customizing ablative algorithms for use in surgery; (ii) the nature of pre-perturbation data; (iii) the nature of post-perturbation data, including clarifying that a “perturbation” is different from the corrective operative procedure; and (iv) selection and updating are not separate steps (a surgical instrument has an associated ablative algorithm; thus, the previously presented claims should have been directed to “selective updating” rather than “selection” and

“updating”). Support for said claim exists throughout the specification and original claims. For example, support can be found in paragraphs [0001], [0007], [0026]-[0027]; and Fig. 6 (see 630).

While Applicants assert that the reference to claim 1 in claim 40 does not make claim 40 a dependent claim, in the interest of advancing prosecution Applicants have amended claim 40 to instead recite the language of amended claim 1.

Applicants have amended claim 41 for purposes a clarify in light of the modifications made to claim 1. Support exists, among other places, in amended claim 1 and cancelled claim 11.

Additionally, Applicants have made clarifying amendments to claims 25, 34, 38, 51, and 53 in light of the aforementioned modifications, and in particular to ensure that the language included therein is compatible with the the modifications made to claim 1.

Applicants believe that these amendments further clarify the invention and its novelty, thereby placing the claims in condition for allowance. Furthermore, Applicants assert that no new matter has been added and no new issues have been raised. Therefore, entry of the amendments is respectfully requested.

C. Rejections under 35 U.S.C. §112, 1st paragraph (enablement)

The Examiner has repeated the rejection of claims 1, 7, 8, 11-13, 16, 24-27, 30, 34, 38, 40-43, 46, and 50-54 under 35 USC §112, first paragraph, as failing to comply with the enablement requirement. *See* Office Action, pages 2-3. Applicants respectfully repeat their arguments made in response to the July 7, 2010 Office action that the Office has not established a *prima facie* case of lack of enablement. The Examiner has asked a plethora of questions but has never shown that a skilled artisan would not understand the answers to said questions or would have to resort to undue experimentation in order to answer them. 35 U.S.C. §112, 1st paragraph only requires the specification to be enabled such that a skilled practitioner can make and use the invention without undue experimentation. *See* MPEP §2164.01; *see also*, *In re Wands*, 858 F.2d at 737 (Fed. Cir. 1988). Applicants submit that, from a reading of the specification and the knowledge in the prior art that a skilled practitioner would be able to make

and use the invention without undue experimentation. Thus, the rejection is improper and should be removed.

Although the rejection is improper, Applicants believe that prosecution can be advanced by providing some explanation to the Examiner about the claimed invention while also providing evidence of suitable enablement. It is unreasonable and unnecessary to respond to each of the Examiner's myriad questions, especially when the Examiner states, "[t]he crux of this rejection is how are pre-operative data, post-operative data and predicted post-operative [sic] related?" See Office Action, page 2. In answer to this, it is important to explain the various types of data, as it appears to Applicants that there may be some confusion between the terms "pre-operative data" and "post-operative data." There are actually two types of "pre-operative data" recited in claim 1—corneal data acquired prior to a perturbation and corneal data acquired after a perturbation but before the corrective surgery. A "perturbation" can be anything that produces a biomechanical response (for example, something as non-invasive as an air puff or something as invasive as a corneal incision), but it occurs before the corrective refractive ophthalmic surgical procedure is performed; it is not the corrective operation itself. Thus, with respect to claim 1, no "post-operative data" is recited. Applicants have described this feature throughout the specification. One non-limiting example is described in Fig. 4, which shows a perturbation 430 occurring prior to ablation 460. In contrast to claim 1, claim 24 does recite true "post-operative data" (i.e., that acquired after a corrective surgical procedure). Applicants assert that all of the aforementioned points are fully enabled.

In light of the above, it should be clear that the instant application is directed to updating a corneal ablative algorithm with individual parameters to achieve a customized ablation algorithm, thereby allowing for customized refractive surgery. See paragraphs [0001], [0005] and [0006]. Pre-operative perturbation of the cornea produces a measurable biomechanical response that facilitates predicting other responses. See paragraph [0048]. Thus, an ablation algorithm can be adjusted based, in part, upon pre-operative corneal measurements (pre-perturbation data, post-perturbation data, or both) of a subject. Such data can, when used in context of a parametric model that stores correlations between corneal measurements and known post-operative outcomes, be used to predict a surgical outcome and update/adjust an ablative

algorithm to increase the odds of achieving the desired/predicted surgical outcome. Importantly, the parametric model stores empirically- and/or statistically-derived correlations between corneal measurements and post-operative outcomes. See paragraphs [0051]; [0027]-[0033]. The measurements and outcomes giving rise to said stored correlations are distinct from those of the patient for which the ablative surgical algorithm is being customized. Thus, the parametric model allows for a statistical comparison of an individual patient's pre-operative corneal data and desired/predicted surgical outcome with the corneal data and known surgical outcomes of a plurality of previously treated patients (this is the nature of a parametric model). Applicants assert that all of the aforementioned points are fully enabled.

Selective updating of the ablation algorithm is based, at least in part, on the pre-operative data (i.e., one or both of pre-perturbation data and post-perturbation data), thereby allowing individual corneal biomechanical properties to be accounted for in determining/modifying an ablation profile to deliver the desired surgical outcome for that cornea. A processor analyzes the received pre-operative corneal data in light of the parametric model and one or more correlations stored therein and identifies ways to update a surgical ablative algorithm. See paragraph [0041]. Updating may involve enhancing certain aspects of an algorithm, diminishing other aspects, adding aspects, or deleting aspects, wherein such modification of the algorithm is based, at least in part, upon one or more correlations between the pre-operative corneal data of an individual patient and a desired surgical outcome. See paragraph [0059]. Thus, updating is based, at least in part, upon how closely the individual patient's corneal data compares to that of a plurality of previously treated patients for whom surgical outcomes are known, and the inclusion, exclusion, and importance of particular corneal data/correlation in the updating process depends upon statistical influence of such data/correlation upon a surgical outcome (this is the nature of a parametric model). There are no pre-determined outcomes; updating is based upon statistical correlations between pre-operative corneal data and post-operative outcomes. Examples of correlations between pre-operative corneal data and surgical outcomes can be found in paragraphs [0006], [0007], [0051], [0052], [0055], [0065], [0066], and [0067]. A processor selectively updates the ablative algorithm, resulting in a surgical algorithm customized for the cornea on which a refractive ophthalmic surgery will be performed. Applicants assert that all of the aforementioned points are fully enabled.

Applicants believe that the aforementioned comments demonstrate that enablement exists and that the rejection under 35 USC §112, 1st paragraph, is improper. The statute only requires that sufficient description be provided to allow a skilled practitioner to make and use the invention without undue experimentation. *See* MPEP §2164.01. Moreover, it is not necessary to provide detailed procedures for making and using the invention. *See* MPEP §2164. Applicants have demonstrated that enablement exists. The Examiner has not provided any evidence that a skilled practitioner would not be able to make and use the invention without undue experimentation. Accordingly, Applicants respectfully request that the rejection be withdrawn.

D. Rejections under 35 U.S.C. §112, 2nd paragraph

The Office has rejected claims 1, 30 and 41 under 35 U.S.C. §112, 2nd paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. *See* Office Action, page 4.

With respect to claims 1 and 41, the Examiner states, “[i]t is unclear how data can be characterized as post-perturbation data if the surgery has not yet been performed.” *See*, Office action page 4. “Post-perturbation data” is a measured biomechanical response to a pre-operative perturbation. As described above, a “perturbation” can be anything that produces a biomechanical response (for example, something as non-invasive as an air puff or something as invasive as a corneal incision), provided that it occurs before the corrective refractive ophthalmic surgical procedure is performed. Applicants submit one of skill in the art, especially after referencing Fig. 4 (which visually delineates a perturbation 430 occurring prior to ablation 460) would understand that “post-perturbation data” is data acquired prior to a corrective surgical procedure. One of skill in the art would also understand that because the corrective surgical procedure occurs after a surgical algorithm is updated and because updating may be based (at least in part) upon post-perturbation data, a perturbation must not be the same as the corrective surgical procedure. Thus, Applicants submit that all terms are unambiguous and that the boundaries of the claims are properly delineated.

With respect to claim 30, the rejection is moot. Applicants have cancelled the claim without prejudice or disclaimer.

In light of the aforementioned, Applicants respectfully request withdrawal of the rejections and allowance of claims 1 and 41.

E. Rejections under 35 U.S.C. §112, 4th paragraph

The Office has rejected claims 24, 30, 38, and 40 under 35 U.S.C. §112, 4th paragraph, as being dependent claims that do not further limit the subject matter of the claims from which they depend. *See* Office action, page 4.

With respect to claim 24, Applicants submit that the rejection is improper because the claim further limits the subject matter of both claims 50 (from which it depends) and 1 (from which claim 50 depends). Notably, nothing in claims 1 or 50 recites patient visual performance data on which the refractive surgery was performed (i.e., post-surgical data). Therefore, claim 24 clearly imposes additional limitations on the subject matter of claims 1 and 50. Accordingly, Applicants respectfully request removal of the rejection and allowance of the claim.

With respect to claim 30, the rejection is moot. Applicants have cancelled the claim without prejudice or disclaimer.

With respect to claim 38, Applicants submit that the rejection is improper because the claim further limits the subject matter of claim 1. Notably, nothing in claim 1 recites a laser eye surgery apparatus nor does claim 1 recite storing an ablation program, corneal data, and a parametric model in the memory of said apparatus. Therefore, claim 38 clearly imposes additional limitations on the subject matter of claim 1. Accordingly, Applicants respectfully request withdrawal of the rejection and allowance of the claim.

With respect to claim 40, the rejection is moot. Applicants' amendment has clarified that claim 40 is an independent claim. Thus, 35 U.S.C. §112, 4th paragraph, is not applicable.

In light of the aforementioned, Applicants respectfully request withdrawal of the rejections and allowance of claims 24, 38, and 40.

F. Rejections under 35 U.S.C. §102

The Office has rejected claims 1, 7, 8, 11-13, 16, 24-27, 30, 34, 38, 40-43, 46, and 50-54 under 35 U.S.C. §102(b) as being anticipated by Rajan et al. (US 5,891,131). *See* Office Action, pages 4-5. Applicants respectfully disagree and assert that because Rajan fails to teach every element of independent claims 1, 40, and 41 no anticipation exists with respect to these claims or any claims depending therefrom.

Amended claim 1 recites the limitation “parametric model storing one or more correlations between corneal data and post-operative results.” Nowhere in Rajan is there any discussion whatsoever of a parametric model. The model of Rajan is a mechanistic model that uses only data from an individual. Nowhere in Rajan is there use of statistical correlations between corneal measurements and known post-operative outcomes of a plurality of patients to predict a surgical outcome and update/adjust an ablative algorithm to increase the odds of achieving the desired/predicted surgical outcome. In fact, use of a parametric model in the method of Rajan would change the principle of its operation. In light of the aforementioned, Rajan does not teach each and every element of claim 1.

Independent claim 40 is limited by the method described in claim 1. Therefore, Rajan does not teach each and every element of claim 40 for the reasons cited above.

Independent claim 41 comprises “a computer readable medium having stored thereon a parametric model” As previously indicated herein, Rajan lacks any teaching or suggestion of a parametric model. Thus, Rajan does not teach each and every element of claim 41.

MPEP § 2131 instructs that a claim is anticipated only if a prior art reference teaches each and every element as set forth in the claim. Since Rajan lacks disclosure of all of the elements of Applicants' claims as described above, Rajan cannot anticipate the claims. Therefore, Applicants respectfully assert that independent claims 1, 40, and 41 are patentably distinguishable over Rajan, and as such, the rejection should be withdrawn and the claims allowed. When an independent claim is not anticipated, then any claim depending therefrom also cannot be anticipated. *See Monsanto Co. v. Syngenta Seeds, Inc.*, 503 F.3d 1352, 1357 (Fed. Cir. 2007) (“[a] claim in dependent form shall be construed to incorporate by reference all

the limitations of the claim to which it refers.”). Accordingly, Applicants also respectfully request withdrawal of the rejection of the dependent claims and allowance thereof.

G. Conclusions

Applicants have amended certain claims for purposes of clarity, and not for purposes of distinguishing over the prior art. In light of such clarifying amendments, clarifying statements about the nature of the invention, and the arguments recited herein, Applicants assert that there is no reasonable basis for maintaining the rejections under 35 U.S.C. §112 and 35 U.S.C. §102 and that the claims are in condition for allowance. Thus, Applicants respectfully request withdrawal of all grounds of rejection and a Notice of Allowance be issued.

It is believed that no additional fees are necessary in connection with the filing of this paper. However, if the Commissioner determines that additional fees are necessary, or if a petition is required for acceptance of the same, the Commissioner is hereby authorized to charge Deposit Account No 041133 for any such fees, and Applicants hereby make any such petition.

Date: June 10, 2011

Respectfully submitted,
Dinsmore & Shohl, LLP,
/joel B. cloud/
Joel B. Cloud
Reg. No. 56,764
(614) 628-6933
(614) 628-6890 (fax)

jcloud@dinslaw.com